

§ 1310.21

drug products, in the form and quantity listed in the application submitted (indicated as the “date”) are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved].			

[60 FR 32463, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

§ 1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

(a) A Federal department or agency may not sell from the stocks of the department or agency any chemical which, as determined by the Administrator of the Drug Enforcement Administration, could be used in the manufacture of a controlled substance, unless the Administrator certifies in writing to the head of the department or agency that there is no reasonable cause to believe that the sale of the specific chemical to a specific person would result in the illegal manufacture of a controlled substance. For purposes of this requirement, reasonable cause to believe means that the Administration has knowledge of facts which would cause a reasonable person to reasonably conclude that a chemical would be diverted to the illegal manufacture of a controlled substance.

(b) A Federal department or agency must request certification by submitting a written request to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: Domestic Chemical Control Unit (ODID). A request for certification may be transmitted directly to the Drug Enforcement Administration, Domestic Chemical Control Unit through electronic facsimile media. A request for certification must be submitted no later than fifteen calendar days before the proposed sale is to take place. In order to facilitate the sale of chemicals from Federal departments’ or agencies’ stocks, Federal departments or agen-

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cies may wish to submit requests as far in advance of the fifteen calendar days as possible. The written notification of the proposed sale must include:

- (1) The name and amount of the chemical to be sold;
- (2) The name and address of the prospective bidder;
- (3) The name and address of the prospective end-user, in cases where a sale is being brokered;
- (4) Point(s) of contact for the prospective bidder and, where appropriate, prospective end-user; and
- (5) The end use of the chemical.

(c) Within fifteen calendar days of receipt of a request for certification, the Administrator will certify in writing to the head of the Federal department or agency that there is, or is not, reasonable cause to believe that the sale of the specific chemical to the specific bidder and end-user would result in the illegal manufacture of a controlled substance. In making this determination, the following factors must be considered:

- (1) Past experience of the prospective bidder or end-user in the maintenance of effective controls against diversion of listed chemicals into other than legitimate medical, scientific, and industrial channels;
- (2) Compliance of the prospective bidder or end-user with applicable Federal, state and local law;
- (3) Prior conviction record of the prospective bidder or end-user relating to listed chemicals or controlled substances under Federal or state laws; and
- (4) Such other factors as may be relevant to and consistent with the public health and safety.

(d) If the Administrator certifies to the head of a Federal department or agency that there is no reasonable cause to believe that the sale of a specific chemical to a prospective bidder and end-user will result in the illegal manufacture of a controlled substance, that certification will be effective for one year from the date of issuance with respect to further sales of the same chemical to the same prospective bidder and end-user, unless the Administrator notifies the head of the Federal department or agency in writing that the certification is withdrawn. If the

certification is withdrawn, DEA will also provide written notice to the bidder and end-user, which will contain a statement of the legal and factual basis for this determination.

(e) If the Administrator determines there is reasonable cause to believe the sale of the specific chemical to a specific bidder and end-user would result in the illegal manufacture of a controlled substance, DEA will provide written notice to the head of a Federal department or agency refusing to certify the proposed sale under the authority of 21 U.S.C. 890. DEA also will provide, within fifteen calendar days of receiving a request for certification from a Federal department or agency, the same written notice to the prospective bidder and end-user, and this notice also will contain a statement of the legal and factual basis for the refusal of certification. The prospective bidder and end-user may, within thirty calendar days of receipt of notification of the refusal, submit written comments or written objections to the Administrator's refusal. At the same time, the prospective bidder and end-user also may provide supporting documentation to contest the Administrator's refusal. If such written comments or written objections raise issues regarding any finding of fact or conclusion of law upon which the refusal is based, the Administrator will reconsider the refusal of the proposed sale in light of the written comments or written objections filed. Thereafter, within a reasonable time, the Administrator will withdraw or affirm the original refusal of certification as he determines appropriate. The Administrator will provide written reasons for any affirmation of the original refusal. Such affirmation of the original refusal will constitute a final decision for purposes of judicial review under 21 U.S.C. 877.

(f) If the Administrator determines there is reasonable cause to believe that an existing certification should be withdrawn, DEA will provide written notice to the head of a Federal department or agency of such withdrawal under the authority of 21 U.S.C. 890. DEA also will provide, within fifteen calendar days of withdrawal of an existing certification, the same written notice to the bidder and end-user, and

this notice also will contain a statement of the legal and factual basis for the withdrawal. The bidder and end-user may, within thirty calendar days of receipt of notification of the withdrawal of the existing certification, submit written comments or written objections to the Administrator's withdrawal. At the same time, the bidder and end-user also may provide supporting documentation to contest the Administrator's withdrawal. If such written comments or written objections raise issues regarding any finding of fact or conclusion of law upon which the withdrawal of the existing certification is based, the Administrator will reconsider the withdrawal of the existing certification in light of the written comments or written objections filed. Thereafter, within a reasonable time, the Administrator will withdraw or affirm the original withdrawal of the existing certification as he determines appropriate. The Administrator will provide written reasons for any affirmation of the original withdrawal of the existing certification. Such affirmation of the original withdrawal of the existing certification will constitute a final decision for purposes of judicial review under 21 U.S.C. 877.

[68 FR 62737, Nov. 6, 2003]

PART 1311—DIGITAL CERTIFICATES

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